VZCZCXRO8749
PP RUEHMA RUEHPA
DE RUEHUJA #0448/01 0721319
ZNR UUUUU ZZH
P 131319Z MAR 09
FM AMEMBASSY ABUJA
TO RUEHC/SECSTATE WASHDC PRIORITY 5508
INFO RUEHOS/AMCONSUL LAGOS PRIORITY 0967
RUEHGB/AMEMBASSY BAGHDAD 0105
RUEHZK/ECOWAS COLLECTIVE
RUEHPH/CDC ATLANTA GA
RUEAUSA/DEPT OF HHS WASHDC
RUCPDOC/DEPT OF COMMERCE WASHDC
RUEAWJA/DEPT OF JUSTICE WASHDC

UNCLAS SECTION 01 OF 03 ABUJA 000448

SENSITIVE SIPDIS

DEPARTMENT FOR OES/IHA WILUSZ AND PASS TO USTR FOR AGAMA; PTO FOR HICKEY; LOC FOR USCO PPINHA
USAID FOR GH; AFR/SD; AND AFR/WA
BAGHDAD FOR DUNDAS MCCULLOUGH
CDC FOR NCIRD/GID/DEEB ERBER
DHHS/OGHA FOR ADENIYI JONES
DHHS/CDC/COGH FOR BLOUNT
DHHS/CDC/NCHHSTP/GAP FOR BIRX
DHHS/CDC/NCEH FOR LEWIS
DHHS/FDA FOR ALCOCK
DOJ FOR MKOUAME
USDOC FOR 3317/ITA/OA/KBURRESS AND 3130/USFC/OIO/ANESA/MCREED

E.O. 12958: N/A

TAGS: TBIO EAID KIPR ECON SOCI ETRD NI

SUBJECT: NIGERIA: USG-GON RAPID RESPONSE STEMS ACUTE RENAL FAILURE OUTBREAK

SENSITIVE BUT UNCLASSIFIED - DO NOT DISTRIBUTE OUTSIDE USG.

 $\P1.$ (SBU): SUMMARY: Following reports of an unusually high number of cases of acute renal failure (ARF) among Nigerian children between November 2008 and January 2009, the USG dispatched a team of experts which assisted with conducting epidemiological investigations, developing and launching an effective public health media campaign, and inspecting a local manufacturer of a contaminated teething mixture sold as "MY PIKIN." USG and Nigerian experts concluded that the ingestion of "MY PIKIN" contaminated with diethylene glycol was the main cause of the outbreak. A total of 111 children aged six to forty eight months were diagnosed with ARF and eighty-four died. Mortality and morbidity from the diethylene glycol poisoning is likely to be under-estimated given poor surveillance and reporting practices. Nigerian government authorities closed the Lagos-based "MY-PIKIN" manufacturing plant in November 2008 and on February 12 arrested twelve individuals suspected to be associated with the manufacturing and distribution of the tainted product. Strong cooperation and excellent ties between the USG and GON were instrumental in positively determining the ARF outbreak, identifying possible risk factors, in back tracing the source and distribution network of the tainted teething mixture, and in launching effective intervention strategies to stymie the outbreak. END SUMMARY.

ARF OUTBREAK

12. (U) In mid November 2008, the Nigerian Federal Ministry of Health (FMOH) received a report involving 13 pediatric cases of ARF in the preceding three weeks from a hospital in Lagos. These children were under the age of four and initially displayed nonspecific febrile illness, which progressed rapidly to ARF. In subsequent weeks the ministry received similar reports from Kaduna, Oyo and Osun states. (Note: ARF is a sudden deterioration of renal function resulting in the inability to maintain fluid and electrolyte balance and is difficult to determine its primary cause without an epidemiological investigation. It is rare in children and generally reversible, if discovered early. End Note).

- ¶3. (U) Following reports of several ARF cases, the Nigeria National Agency For Food and Drug Administration (NAFDAC) conducted preliminary product investigation and identified the locally-manufactured teething product "MY PIKIN" as the contaminated product causing the outbreak. On November 21, NAFDAC closed the "MY PIKIN" manufacturing plant, launched a product recall, and issued a press releases warning the public about the contaminated "MY PIKIN." NAFDAC also briefed both chambers of parliament on the ARF outbreak and actions being taken to combat it. In response to a request from the FMOH, the U.S. in-country Center for Disease Control and Prevention (CDC) facilitated a preliminary hospital record review and conducted site visits of pediatric ARF cases in Kaduna, Lagos, Oyo and Osun states. The review was conducted by residents of the U.S.-funded Field Epidemiology and Laboratory Training Program (FELTP). (Note: the FELTP trains young and upcoming Nigerian epidemiologists to conduct field investigations of disease outbreaks and toxic contaminations. End Note).
- 14. (U) The FELTP preliminary record review provided an estimate of the morbidity and mortality associated with the contamination. Laboratory analysis of samples of "MY PIKIN" indicated varying levels of diethylene glycol (DEG) contamination (up to 90%). (Note: DEG is an odorless, colorless, and sweet testing compound used in industrial solvents and antifreeze. End Note). According to CDC experts, to date, there have been nine ARF outbreaks associated with DEG contamination worldwide. The first outbreak was in the United States in 1937, which caused 105 deaths from contaminated sulfanilamide elixir. Nigeria experienced an ARF outbreak in 1990,

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associated with contaminated acetaminophen, which resulted in 47 deaths.

U.S. DISPATCHES EXPERTS TO ASSIST WITH OUTBREAK

- 15. (U) A USG investigation team arrived in mid January 2009 and over a period of three weeks performed epidemiological investigations and analysis, conducted site visits and case-family interviews, and collected and tested medications found in case-family homes. The team investigated a total of 112 cases, 57 of which were confirmed as having developed ARF consistent with poisoning. Of the 57 positive cases, 55 were determined to have been exposed to the contaminated "MY PIKIN." The team also developed and put in place an enhanced surveillance system for further monitoring and reporting of ARF cases.
- 16. (U) A CDC expert in communication planning, a member of the USG response team, worked with a Nigerian interagency panel of communication experts to develop and launch an effective public health communication plan. The plan included a media campaign, which provided accurate and timely information about the contaminated product and available medical assistance to the general public.
- 17. (U) A U.S. Federal Food and Drug Administration (FDA) Product Inspector, another member of the USG response team, worked closely with Federal and Lagos Region NAFDAC officials and revamped NAFDAC operational standards for incidents of this kind, including a standardized checklist for site inspections of manufacturing facilities. A site visit of the "MY PIKIN" manufacturer, Barewa Pharmaceuticals Ltd was conducted in Lagos. It was determined that the manufacturer's poor recordkeeping practices hindered efforts to identify and stop further distribution of contaminated lots of "MY PIKIN."

USG TEAM CONCLUSION AND RECOMMENDATIONS

 $\P8$. (U) Investigation of the majority of reported cases of ARF confirmed exposure to "MY PIKIN," even though inferences of causation are complicated by the presence of multiple drug exposures. Potentially life-threatening DEG-induced toxicity

continues to be a public health problem due to residual "MY PIKIN" remaining in households, in some health facilities, and in market circulation by itinerant and unscrupulous drug vendors. The USG team provided the following recommendations to the GON before its departure:

- -- Further public health campaign be conducted to heighten awareness of the dangers of contaminated "MY PIKIN."
- -- Guidance to parents, physicians and pharmacists on how to forfeit leftover "MY PIKIN" medications be issued.
- -- Create a mechanism to track surrendered medications to fully account for contaminated batches and their raw ingredients.
- -- Targeted education campaign for parents on appropriate treatments for teething and the dangers of using poly-pharmacy be conducted.
- -- Heightened ARF surveillance should continue until the drug recall efforts can reasonably account for and recover the preponderance of medication manufactured.
- 19. (SBU) COMMENT: The GON's swift reaction and USG's critical technical assistance has mitigated the impact of an ARF outbreak in Nigeria. The U.S. Mission will monitor the situation closely and follow the implementation of the recommendations. Nigeria lacks a safe drug manufacturing, procurement and distribution system, which has lead to substandard pharmaceutical products and the flourishing

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of illegal markets for fake and counterfeit drugs. The problem is compounded by a weak and overburdened public health system that is incapable of effectively responding to drug-induced or other types of outbreaks. The USG-funded Field Epidemiology and Laboratory Training Program (FELTP), which started training Nigeria epidemiologists in 2007, is enhancing Nigeria's ability to better respond to public health emergencies. END COMMENT.

110. (U) This cable was coordinated with Consulate Lagos.

SANDERS